



CASE LA236 CIP-1

CERTIFICATE OF MAILING

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231.

John M. Kilcoyne  
Type or print name

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**Signature**

September 26, 2001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**IN RE APPLICATION OF**

Art Unit: 1615

TIMMINS ET AL.

Examiner: P. Kulikosky

APPLICATION NO: 09/398,107

FILED: SEPTEMBER 16, 1999

**FOR: BIPHASIC CONTROLLED RELEASE DELIVERY SYSTEM FOR HIGH SOLUBILITY PHARMACEUTICALS AND METHOD**

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Assistant Commissioner for Patents  
Washington, D.C. 20231

## INFORMATION DISCLOSURE STATEMENT

Sir:

This Information Disclosure Statement is being filed in accordance with 37 C.F.R. §1.97(c). A letter for payment of fee set forth in 37 C.F.R. §1.17(p) is enclosed.

In accordance with 37 C.F.R. §1.56, applicants wish to call the Examiner's attention to the documents cited on the attached form(s) PTO-1449.

Copies of these documents are enclosed herewith.

The Examiner is requested to consider the foregoing information in relation to this application and indicate that each document was considered by returning a copy of the initialed PTO 1449 form(s).

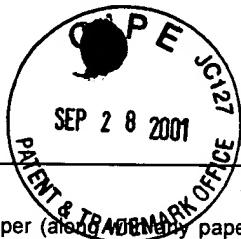
10/02/2001 MBERHE 00000113 193880 09398107

02 FC:126 180.00 CH

Respectfully submitted,

Bristol-Myers Squibb Company  
Patent Department  
P.O. Box 4000  
Princeton, NJ 08543-4000  
Date: September 26, 2001

John M. Kilcoyne  
John M. Kilcoyne  
Attorney for Applicants  
Reg. No. 33,100  
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CASE LA23b CIP-1

CERTIFICATE OF MAILING

I hereby certify that this paper (also known as paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231.

John M. Kilcoyne  
Type or print name

*John M. Kilcoyne*  
Signature

September 26, 2001  
Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE *#12*

IN RE APPLICATION OF

Art Unit: 1615

TIMMINS ET AL.

Examiner: P. Kulkosky

APPLICATION NO: 09/398,107

FILED: SEPTEMBER 16, 1999

FOR: BIPHASIC CONTROLLED RELEASE DELIVERY SYSTEM FOR  
HIGH SOLUBILITY PHARMACEUTICALS AND METHOD

Assistant Commissioner for Patents  
Washington, D.C. 20231

FEE LETTER FOR INFORMATION DISCLOSURE STATEMENT

Sir:

Please charge Deposit Account No. 19-3880 in the name of Bristol-Myers Squibb Company in the amount of \$180 for payment of the fee pursuant to 37 CFR §1.17(p) for the submission of an Information Disclosure Statement under 37 CFR §1.97(c).

An additional copy of this paper is here enclosed. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 19-3880 in the name of Bristol-Myers Squibb Company.

Respectfully submitted,

Bristol-Myers Squibb Company  
Patent Department  
P.O. Box 4000  
Princeton, NJ 08543-4000  
(609) 252-5909  
Date: September 26, 2001

*John M. Kilcoyne*  
John M. Kilcoyne  
Attorney for Applicants  
Reg. No. 33,100

TECH CENTER 1600/2900

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#12

9/28/01

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF  
TIMMINS ET AL.

Art Unit: 1615

Examiner: J. Spear

APPLICATION NO: 09/398,107

FILED: SEPTEMBER 16, 1999

FOR: BIPHASIC CONTROLLED RELEASE DELIVERY SYSTEM FOR  
HIGH SOLUBILITY PHARMACEUTICALS AND METHODAssistant Commissioner for Patents  
Washington, D.C. 2023102 MAR 25 AM 9:26  
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U.S. PATENT AND TRADEMARK OFFICE  
1600/2980INFORMATION DISCLOSURE STATEMENT

Sir:

As requested, attached are copies of the Information Disclosure Statements dated July 14, 1998, and September 16, 1999, already submitted in this application.

Also attached is an Information Disclosure Statement listing

- (i) U.S. Patent No. 6,340,475 (recently issued on January 22, 2002) and U.S. 2001/0018070 (published August 30, 2001) which are both in the patent family for WO 98/55107 which was already cited herein, and
- (ii) U.S. Patent No. 5,955,106 (issued September 21, 1999) which is in the patent family for ZA 957670 also already cited herein.

The Examiner is requested to consider the foregoing information in relation to this application and indicate that each document was considered by returning a copy of the initialed PTO 1449 form(s).

Respectfully submitted,

Bristol-Myers Squibb Company  
Patent Department  
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Princeton, NJ 08543-4000  
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John M. Kilcoyne  
John M. Kilcoyne  
Attorney for Applicants  
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Date: *March 21, 2002*

#12

Patent  
Case No. LA23b

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Peter Timmins et al  
Filed: Herewith  
For: BIPHASIC CONTROLLED RELEASE DELIVERY SYSTEM FOR  
HIGH SOLUBILITY PHARMACEUTICALS AND METHOD

Princeton, New Jersey 08543-5000  
September 16, 1999

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INFORMATION DISCLOSURE STATEMENT

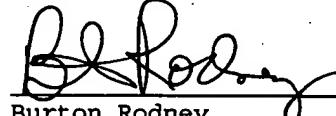
To the Commissioner of Patents and Trademarks:

This information disclosure statement is being presented as a means of complying with the requirements of 37 CFR 1.56. It includes what the undersigned believes to be the closest prior art. However, no representation is made that better art does not exist nor that a search has been made.

Copies of references were provided in previous patent application Serial No. 09/044,446 filed 03/19/98 (copies of Information Disclosure Statement and Form PTO-1449 are attached), and the following reference was cited by the Examiner, WO 96/08243 PCT (South African counterpart Patent Application No. 95/7670 is enclosed)

Copies of the following additional references are enclosed: Noel, M., "Kinetic study of normal and sustained release dosage forms of metformin in normal subjects"; and Karttunen, P. et al., "The pharmacokinetics of metformin: a comparison of the properties of a rapid-release and a sustained-release preparation".

Respectfully submitted,

  
Burton Rodney  
Attorney

BR:mz  
Enclosures  
(609) 252-4336